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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/102,865 06/23/98 RAJU S P1096R1

GENENTECH INC
1 DNA WAY
SOUTH SAN FRANCISCO CA 94080-4990

HM12/0201

EXAMINER

SCHWADRON, R

ART UNIT

PAPER NUMBER

1644

10

DATE MAILED:

02/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/102,865

Applicant(s)

Raju

Examiner

Ron Schwadron, Ph.D.

Group Art Unit

1644



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-29 is/are pending in the application.
- Of the above, claim(s) 10-24 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-9 and 25-29 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit 1644

1. Applicant's election without traverse of Group I, claims 1-9,25-29 in Paper No.9 is acknowledged.

2. Claims 10-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected inventions. Election was made **without** traverse in Paper No. 9.

3. Claims 1-9,25-29 are under consideration.

4. Applicant has not complied with one or more conditions for receiving the benefit of a filing date under 35 U.S.C. 119(e). An application in which the benefits of an earlier application are desired must contain a specific reference to the earlier filed application(s) in the first sentence of the specification (37 CFR 1.78). A statement reading "This application claims priority to Provisional Application Serial No. 60/004458, filed 9/28/95" should be entered following the title of the invention or as the first sentence of the specification.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b)

6. Claims 1-9,25-29 are provisionally rejected under the judicially created doctrine of

obviousness-type double patenting as being unpatentable over claims 1-7,10-16,20,35-39,41-44 of copending Application No. 09/183824. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the two sets of claims differ in scope, both sets of claims encompass compositions/articles of manufacture that comprise the glycoprotein with the properties recited in claim 1 of the instant application. Therefore the two sets of claims would have been prima facie obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5,25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumpel et al.

Kumpel et al. teach human monoclonal antibodies wherein substantially all of the oligosaccharide found on said antibody is G2 (see Table 1, columns 1-3, and page 149, column 1, first incomplete paragraph). Said antibodies are in composition form wherein they are contained in a pharmaceutically acceptable carrier (eg. tissue culture media). The antibody 2B6 disclosed in Table 1 is an IgG1 antibody (see page 144, second column).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-9,25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumpel et al. in view of Maras et al. (US Patent 5,834,251) and prior art disclosed in the specification

(pages 1,2,19-21).

Kumpel et al. teach human monoclonal antibodies wherein substantially all of the oligosaccharide found on said antibody is G2 (see Table 1, columns 1-3, and page 149, column 1, first incomplete paragraph). Said antibodies are in composition form wherein they are contained in a pharmaceutically acceptable carrier (eg. tissue culture media). The antibody 2B6 disclosed in Table 1 is an IgG1 antibody (see page 144, second column). Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Kumpel et al. do not teach the molecules of claims 6-9 or the claimed articles of manufacture. Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (see columns 12 and 16). Kumpel et al. teach that said enzyme is involved in the production of G2 oligosaccharides (see abstract). The prior art recited in the specification (pages 1,2,19-21) discloses that the antibodies, immunoadhesions and chimeric molecules recited in claims 6-9 were known in the art, as was the clinical use of said molecules. It would have been prima facie obvious to one of ordinary skill in the art to have created G2 oligosaccharide versions of the art known molecules recited in claims 6-9 because Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (eg. to produce G2 oligosaccharide glycoproteins). One of ordinary skill in the art would have been motivated to do the aforementioned in order to produce G2 versions of the aforementioned glycoproteins for potential clinical evaluation. Said G2 glycoproteins would have been produced as the claimed articles of manufacture for use in clinical trials.

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 *lbo*



Ron Schwadron, Ph.D.

Primary Examiner

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